REMARKS

With the entry of the present amendment, Claims 1-22, 25-39, 41-42, 44, 46, 47-48, and 50-54 are pending in this application. Claims 2-6, 20-22, 36, 42, 46, and 50 have been amended, and Claims 23-24, and 55-57 have been cancelled. For the reasons described below, it is believed that all claims are in condition for allowance.

Claim Objection

Claim 23 was objected to under 37 CFR 1.75 as being a substantial duplicate of Claim 22. As Claim 23 has been cancelled, it is believed that this objection is now moot.

Allowable Subject Matter

Claims 48 and 50-54 have been allowed. Claim 50 has been amended to properly depend from allowed Claim 48.

Claim 46 was objected to as being dependent on a rejected base claim, but the Examiner indicated that Claim 46 was otherwise allowable. Claim 46 has been amended to incorporate all the limitations of the base claim, and it is believed that this claim is now in condition for allowance.

Claim Rejections

Claims 1-22, 25-39, 41-42, 44, and 47 stand rejected under 35 U.S.C. §102 and/or 35 U.S.C. §103. It is believed that with the entry of the present Amendment, these rejections are all overcome. For the Examiner's convenience, applicants will first address Claims 1-19 and 22, which relate to partially disposable modular hearing devices, then Claims 25-39 and 41-42, which relate to a flexible tip for a hearing device containing a vibrator isolator portion, and finally Claims 44 and 47, which relate to a potting material which pots the interior of a hearing device.

A. Partially Disposable Modular Hearing Devices (Claims 1-19 and 22)

In one aspect, the present invention relates to partially disposable modular hearing devices, such as recited in amended Claims 1-19, and 22. For example, the present invention recognizes and attempts to resolve the inherent conflict between durability and comfort in hearing aid design. Hearing aids are delicate instruments that are intended to perform in the harsh environment of the human ear. To ensure a long useful life (e.g. > 4 years), hearing aids typically employ hard, durable earmold materials to protect the delicate electronics and components contained inside. However, the use of harder, more durable materials results in discomfort to the user. For added comfort, softer, less durable materials could be employed for the earmold, however this would reduce the overall useful life of the device. The present invention resolves this inherent conflict via a modular, partially disposable hearing device, which comprises a base unit, which houses the electronics and other delicate equipment, and a detachable earmold made from a softer, more compliant material. Because the earmold is made from softer, more compliant materials than the base unit, the earmold has a comparitavely shorter useful life. However, the earmold can be mass produced in a competitive manner, and can be easily replaced on a more frequent basis than the base unit. Accordingly, the user is able to achieve the best of both worlds: a highly-durable hearing aid with an long useful life for the most expensive components, and the added comfort of the replaceable, compliant earmold, which can be easily and inexpensively replaced as needed.

In various embodiments, certain components of the hearing device, such as the battery and receiver, can be integrated with the compliant, disposable earmold, and can thus be easily replaced with the replacement of the earmold. In other embodiments, the modular hearing aid comprises an electronics module, which can be easily replaced to accommodate technological advances in hearing-aid electronics.

The modular, partially disposable hearing devices of the present invention, as recited in amended Claims 1-19, and 22, are not taught or suggested by the prior art, as explained in more detail below. Accordingly, it is respectfully submitted that these claims are allowable.

In the present Office Action, Claims 1 and 8-10 were rejected under 35 U.S.C. §103 as unpatentable over Voroba, *et al.*, 4,870,688 ("Voroba"), or Weeks, 5,748,743 ("Weeks"), in view

of Juneau, *et al.*, 6,434,248 ("Juneau '248"). In a separate rejection, Claims 1-10 were rejected as unpatentable over Diethelm, 3,852,540 ("Diethelm"), in view of Voroba and Juneau '248.

The Examiner acknowledges that Voroba, Weeks, and Diethelm do not teach an earmold having a shorter useful life than the base unit. However, the Examiner asserts that it would have been obvious to have done so, because Voroba and Weeks discuss an earmold having compliant materials, and Juneau '248 discusses a rigid faceplate/base unit. However, none of the prior art references discuss the relative useful lives of the hearing aid components, and none of them even remotely suggest to provide an earmold having a shorter useful life than the base unit.

NOT IN CLAIM

The present inventors alone recognize the inherent conflict between durability and comfort in the design of hearing devices, and resolved this conflict in a unique manner. Specifically, the hearing device of the present invention intentionally employs a compliant earmold having a shorter useful life than the base unit, but which is designed to provide added user comfort. None of the prior art references recognize or discuss the inherent conflict between durability and comfort, nor do any of the references discuss the relative useful lives of the various components, or suggest the novel approach of the present invention. The present invention identifies and solves a problem that is neither recognized nor addressed by the cited prior art, which is a factor supporting the nonobviousness of present Claim 1. See M.P.E.P. §2141.02.

relative term of degree.

Moreover, the Examiner is obliged to consider the teachings of the prior art "as a whole," including portions which would lead away from the claimed invention. (See M.P.E.P. §2141.02). The Voroba, Weeks, Diethelm, and Juneau '248 patents contain no teaching or suggestion regarding the relative useful lives of a base unit and earmold, and applicants submit that when considered "as a whole," it is clear that it is an *a priori* assumption in each of the cited patents that the entire device, including the base unit and earmold, has a single useful lifetime. In Voroba, for instance, the earshell consists of a "solid core or shell 20," to which softer layers are fixed, which indicates that the earshell is intended to have a useful life as long as that of the base unit. Also, Voroba teaches that the earshell is only detached from the base unit in the event of an unanticipated condition (such as physical discomfort or a sound response anomaly), and even then this can only be accomplished with the use of a special "tool." See, e.g., col. 7, lines 45-50. This is inconsistent with the modular, partially disposable design of the present invention, in which the lower-durability earmold is intended to be replaced frequently after use. Also, the

Weeks patent describes "durability" as an important factor in the choice of materials for the ear tip 10, (see col. 3, line 37-40), which, absent any teaching to the contrary, suggests that the ear tip is intended to last as long as the hearing aid assembly 1. In Juneau '248, a soft polymeric body is integrally formed around the electronics and coupled to the face plate, and there is no suggestion that any components have a shorter useful life than any other components. Diethelm is silent as to the materials used in the hearing apparatus, and contains no teaching or suggestion whatsoever regarding the relative useful lives of the components.

It should be further noted that the *only* teaching cited by the Examiner regarding the relative useful lives of the base unit and earmold is taken from *the applicant's own patent disclosure*. (See Office Action, pp. 4 and 6). It is submitted that the citation of the applicants own application, for teachings not found in any of the prior art references, constitutes impermissible hindsight-based obviousness analysis. The teaching or suggetion to make the claimed invention must come from the prior art, not from the applicant's own disclosure. *See In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

hindsight

Also, with respect to the "removable" and "replaceable" earmold of the present invention, the Examiner asserts that Voroba teaches an earshell that is "cut apart" for replacing defective components, and that it is "conceivable" that such a shell would need to be replaced for user comfort. First, it is pointed out that the standard for obviousness or non-obviousness under 35 U.S.C. §103 is not what would be "conceivable" from the teachings of the prior art, but what is actually taught or suggested to by the prior art. Thus, even if the Examiner is correct that something is "conceivable" from the Voroba reference, this would still be insufficient to support a rejection under 35 U.S.C. §103, absent a showing of any actual teaching or suggestion to make the claimed invention. Secondly, it is respectfully submitted that the Examiner may have misinterpreted the teachings of the Voroba patent. The portion of Voroba cited by the Examiner is from the Background section of the patent, and discusses a problem inherent in prior devices, in which the components were permanently sealed inside the ear mold, and could only be accessed by cutting apart the device. However, the Voroba patent proposes to overcome this problem by providing a hearing aid in which the earmold can be detached from the amplification module for servicing using a "special tool," and then reattached for use. In fact, the purpose of providing the "special tool" for detaching and reattaching the earmold and amplification module

or examiner knowledge.

Show Prior Art.

which claim is this?

in Voroba is to avoid the very type of damage (i.e. cutting through the earmold) which the Examiner cites. Voroba teaches to avoid this type of damage, thus preserving the long useful life of the earshell. Therefore, Voroba actually teaches away from a replaceable earmold having a shorter useful life than the base unit, as recited in Claim 1.

As none of the prior art teaches or suggests the hearing device of Claim 1, it is believed that Claim 1 and its dependents, Claims 8-10, are allowable.

Regarding Claims 2-7 and 20-21, Claim 2 has been amended to recite that the removable earmold comprises a battery "non-removably" integrated with the earmold. Claim 4 has been amended to recite that the removable earmold comprises both a battery and a receiver "non-removably" integrated with the earmold. Claim 6 has been amended to recite a removable earmold comprising a receiver and a shell, the receiver housed in the shell and the shell "non-removably" integrated with the earmold. Similarly, Claim 20 has been amended to recite that the removable earmold comprises a battery "non-removably" integrated with the earmold, and Claim 21 has been amended to recite that the removable earmold comprises a battery and receiver "non-removably" integrated with the earmold. It is believed that these amendment place Claims 2-7 in condition for allowance.

For instance, with respect to Claims 2, 4 and 20-21, it is now specified that the battery is "non-removably" integrated with the earmold. This is not taught or suggested in any of the cited references. In fact, Diethelm and Voroba teach away from Claims 2 and 4, because these patents teach hearing devices having batteries which are independently replaceable. (See Voroba, col. 8, lines 44-45: battery 80 "removably housed" by battery compartment 82; see also Diethelm, col. 4, lines 10-11: discussing exchange of voltage source).

With respect to Claim 6, it is now specified that the shell containing the receiver is "non-removably" integrated with the removable earmold. This is not taught or suggested in any of the prior art references. As explained in the previous amendment in this case, the integration of the compliant earmold and the receiver allows the receiver to be placed deep inside the ear canal (particularly due to the soft and flexible earmold) in order to achieve the highest effective sound pressure levels possible. Also, the receiver is very prone to damage, such as when the hearing aid is dropped from a height of several feet onto a hard surface. By integrating the receiver with the

replaceable earmold, a damaged receiver can be easily replaced by the user by simply replacing the entire earmold.

In the present Office Action, the Examiner maintained the rejection of Claim 6, based on the assertion that the reciever in the Voroba patent is "attached to" the amplification module, and not a part of the amplification module, as the applicants had argued. It is believed that with the present amendment, Claim 6 is now patentably distinguishable from the Voroba patent, as Claim 6 now recites that the receiver is "non-removably" integrated with the earmold. Therefore, the receiver cannot be simultaneously "attached to" the amplification module of the base unit, as taught by Voroba, while also "non-removably" integrated with the removable earshell. Accordingly, it is believed that the rejection of Claim 6, and dependent Claim 7, is overcome.

Regarding the rejection of Claims 11-19, it is submitted that the Examiner has failed to make a *prima facie* case of anticipation under §102 or obviousness under §103, because the Office Action fails to acknowledge or address certain features of the claimed invention. In particular, the Examiner failed to consider the claim limitation of a module comprising a shell and electronics, the module *removably* connected to the earmold and *removably* connected to the base unit such that the module can be disconnected from the base unit and the earmold and replaced after use. As noted in the prior amendment in this application, the replaceable module having a shell and electronics, as recited in Claim 11, permits the hearing aid performance to be periodically improved by replacing the electronics module with a new module incorporating the latest advancements in hearing aid electronics (such as integrated circuits), without having to replace the entire hearing aid. See Specification at page 16, line 28 to page 17 line 9. This is not taught or suggested in the cited Voroba patent, or in any of the prior art of record. In Voroba, for instance, all of the electronics are *non-removably* housed in the base unit (i.e. the "amplification module"), and there is no teaching or suggestion to employ a removable electronics module, in addition to the base unit and earmold, as presently claimed. Accordingly, it is submitted that Claim 11 and its dependents, Claims 12-19, are all allowable.

Claim 22 has been amended to recite a method for replacing an earmold of a modular in-the-ear-type hearing aid comprising, *inter alia*, providing a modular hearing aid having a base unit and a compliant earmold having a shorter useful life than the useful life of the base unit, removing the earmold, discarding the earmold, and placing a second earmold onto the base unit.

It is submitted that this amendment places Claim 22 in condition for allowance, as there is no teaching or suggestion in the prior art to provide an earmold having a shorter useful life than the base unit, or to replace the earmold with a second earmold.

B. Flexible Ear Tip with Vibation Isolation Portion (Claims 25-39 and 41-42)

The present invention also relates to a flexible tip for an in-the-ear type hearing aid device. A hearing aid having a flexible tip can have significant advantages, including potentially deep ear canal fittings, efficient coupling of the sound emitted by the receiver to the eardrum, and a corresponding reduction in the required output levels of the receiver. The flexible, compliant tip can also provide a comfortable fit even when it is in the bony region of the ear canal. In one aspect, the present invention comprises a flexible tip having a vibrator isolator portion made from a flexible, compliant material. The vibration isolator portion contains the receiver, and attenuates acoustic vibrations and mechanical vibrations created by the receiver during operation. Also, securing the vibration isolator portion and the receiver within the hearing aid base unit further mechanically decouples the receiver from the base unit. In certain embodiments, the flexible tip also comprises a mushroom shaped tip portion attached to the vibration isolator portion, which forms a seal with the ear canal to attenuate acoustic vibrations produced by the receiver.

A further advantage of this design is that the flexible tip having a vibrator isolator portion, mushroom shaped tip portion, and a sound bore, can be made relatively inexpensively from a flexible, compliant material. A spring, surrounded by the compliant material, can be used to provide the sound bore. The rigid or semi-rigid base unit, containing the microphone, electronics, and other hearing aid components, can then be attached over a portion of the flexible tip for an easy, low-cost assembly method.

With respect to Claim 25, it is submitted that the Examiner has misinterpreted the teachings of the cited Voroba and Diethelm patents. Specifically, neither Voroba nor Diethelm teaches the "flexible earmold tip" comprising a vibrator isolator portion and a receiver, as presently claimed. In Voroba, there is no "flexible" earmold tip. While the earshell of Voroba does include soft layers secured to the exterior of the shell, the patent is clear that the shell itself comprises "a solid core or shell." (See col. 6, line 67). Similarly, Diethelm contains no teaching

or suggestion regarding a flexible earmold tip which contains a vibrator isolator portion, and a receiver. Accordingly, it is believed that Claim 25, and dependent Claims 26-35, are all allowable.

With respect to Claim 36, again neither Voroba nor Diethelm teaches the "flexible earmold tip" comprising a vibrator isolator portion and a receiver, as presently claimed. In Voroba, the tip is a "solid core or shell" affixed with softer layers. Deithelm discusses a "housing" and "protective cap," but does not teach or suggest the flexible earmold tip of the present invention. The secondary reference cited by the Examiner, Baum, discusses an ear insert, such as a hearing-aid earphone or ear protective device, having a plurality of flexible, skirt-like protrusions 41, 42, 43 which create a seal with the ear cavity. However, Baum does not relate to an in-the-ear type device having a base unit with a microphone, battery and electronics. Furthermore, Baum does not teach or suggest a vibrator isolator portion which contains the receiver, and attenuates vibrations from the receiver. Moreover, even if the "flanges" of Baum are incorporated onto the "housing" of Diethelm, as the Examiner proposes on page 10 of the Office Action, this would still not provide the device of Claim 36, because the tip itself would still not be "flexible," as required by Claim 36. Accordingly, it is believed that Claim 36 and its dependents, Claims 37-39 and 41, are also allowable.

Also, for the reasons stated above with respect to Claims 25 and 36, none of the prior art references teach or suggest the method of Claim 42.

C. Potting Material (Claims 44 and 47)

Claims 44 and 47 were rejected under 35 U.S.C. §102(e) as being anticipated by Yoest *et al.*, 6,097,825.

Yoest cannot anticipate or render obvious the hearing device of Claim 44 or the method of Claim 47. Claim 44 recites a base unit adapted to contain a non-replaceable component, and a potting material which pots at least a portion of the inside portion of the base unit, and wherein the material attenuates vibrations caused by the receiver. Claim 47 recites an analogous method of potting the inside of a hearing aid.

The Examiner asserts that Yoest shows the "potting material" of the present claims at reference number 92a. However, Yoest actually states that 92a is "a deformable sponge-like

covering or layer" that is located on the *outside* of the hearing aid housing 90. (See col. 4, lines 14-18; Fig. 4). Therefore, Yoest does not teach or suggest a potting material *inside* the base unit, nor does Yoest teach or suggest providing a potting material to attenuate vibrations from the receiver. In fact, Yoest does not even discuss vibrations from the receiver, or suggest that such vibrations can cause mechanical or acoustical feedback. It appears that Yoest provides the exterior deformable layer to increase comfort, (see col. 4, line 22-23), and does not at all teach or suggest a potting material *inside* the base unit to increase mass and attenuate vibrations from the receiver.

As Yoest fails to disclose the potting material *inside* the base unit, as presently claimed, and because Yoest only discusses a deformable layer *outside* the device for an entirely different purpose than the potting material of the present invention, it is believed that Claims 44 and 47 are allowable.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 341-0036.

Respectfully submitted,

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MARKED UP VERSION OF AMENDMENTS

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

2. (Twice Amended) A modular hearing aid comprising:

a base unit adapted to contain any of a microphone, a receiver, electronics and controls; and

an earmold removably attached to the base unit, the earmold comprising a compliant material, a retention mechanism for connection to the base unit such that the earmold can be connected to the base unit or removed from the base unit and replaced after use, and the earmold comprising a battery non-removably integrated with the earmold.

3. (Amended) The modular hearing aid of Claim 2 wherein the earmold further comprises a shell non-removably integrated with the earmold, the shell housing the battery.

4. (Twice Amended) A modular hearing aid comprising:

a base unit adapted to contain any of a microphone, electronics and controls; and

an earmold removably attached to the base unit, the earmold comprising a compliant material, a retention mechanism for connection to the base unit such that the earmold can be connected to the base unit or removed from the base unit and replaced after use, and the earmold comprising both a battery and a receiver non-removably integrated with the earmold.

5. (Amended) The modular hearing aid of Claim 4 wherein the earmold further comprises a shell non-removably integrated with the earmold, the shell housing the battery and the receiver.

6. (Twice Amended) A modular hearing aid comprising:

a base unit adapted to contain any of a microphone, a battery, electronics and controls; and

an earmold removably attached to the base unit, the earmold comprising a compliant material, a retention mechanism for connection to the base unit such that the earmold can be connected to the base unit or removed from the base unit and replaced after use, and the earmold comprising a receiver and a shell, the shell non-removably integrated with the earmold and the receiver housed within the shell.

20. (Twice Amended) A modular hearing aid comprising:

a base unit adapted to contain a microphone, a receiver, electronics and controls; and

an earmold comprising a compliant material non-removably integrated with a battery, the earmold having a flexible, mushroom shaped earmold tip adapted to create a seal with the bony portion of the ear canal to acoustically isolate the hearing aid base unit from acoustical vibrations created by the receiver, the earmold tip further comprising a retention mechanism for connection to the base unit such that the earmold can be connected to the base unit or removed from the base unit and replaced after use.

21. (Twice Amended) A modular hearing aid comprising:

a base unit adapted to contain a microphone and electronics; and

an earmold comprising a compliant material non-removably integrated with a battery and a receiver, the earmold having a flexible, mushroom shaped earmold tip adapted to create a seal with the bony portion of the ear canal to acoustically isolate the hearing aid base unit from acoustical vibrations created by the receiver, the earmold tip further comprising a retention mechanism for connection to the base unit such that the earmold can be connected to the base unit or removed from the base unit and replaced after use.

22. (Twice Amended) A method for replacing an earmold of a modular in-the-ear-type hearing aid comprising the steps:

providing a modular hearing aid having a base unit and [an] a compliant earmold having a shorter useful life than the useful life of the base unit;

releasing a securing mechanism between the earmold and the base unit, the securing mechanism capable of being released by a user without the use of a separate tool or instrument;

removing the earmold from the base unit;

discarding the earmold;

placing a second earmold onto the base unit; and

attaching the securing mechanism.

36. (Twice Amended) A hearing aid comprising:

a hearing aid base unit having a microphone, a battery and electronics; and

a flexible earmold tip comprising a compliant material and having a vibration isolator portion containing a receiver, a mushroom shaped tip portion adapted to create a seal with an ear canal to acoustically isolate the hearing aid base unit from acoustical vibrations created by [a] the receiver, and a sound bore, the vibration isolator portion enclosed by the base unit and having the receiver electrically attached to the base unit wherein the receiver includes a diaphragm adapted to vibrate in operation causing the receiver to mechanically vibrate and wherein the vibration isolation portion attenuates vibrations from the receiver, the mushroom shaped tip portion being attached to the vibration isolator portion, and the sound bore formed between the vibration isolator portion and the mushroom shaped tip portion and the sound bore providing a channel for the transfer of sound from the receiver to an ear canal of a user.

42. (Twice Amended) A method for attenuating feedback in a hearing aid comprising:

providing a hearing aid base unit, a receiver, and a flexible hearing aid tip comprising a compliant material, the hearing aid tip having a flexible mushroom shaped tip portion and vibration isolator portion;

surrounding the receiver with the vibration isolator portion to attenuate acoustic vibrations and mechanical vibrations created by the receiver during operation;

securing the vibration isolator portion and receiver within the hearing aid base unit; and

placing the hearing aid within an ear such that the mushroom shaped tip portion creates a seal with the bony portion of the ear canal to acoustically isolate the hearing aid base unit from acoustical vibrations created by the receiver.

46. (Amended) [The hearing aid of Claim 44] A disposable hearing aid comprising:

a base unit having an inside portion, the base unit adapted to contain a non-replaceable component, including any of a microphone, a receiver, a battery, electronics and controls; and

a potting material which pots at least a portion of the inside portion of the base unit, wherein the material increases the mass of the hearing aid and wherein the material attenuates vibrations created by the receiver during operation, wherein the potting material forms an acoustical barrier inside the hearing aid between the receiver and the microphone.

50. (Amended) The disposable hearing aid of Claim [49] 48 wherein the layers of fingers comprise an elastomer material.